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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,317	09/16/2005	Kenji Soejima	081356-0247	8219

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,317	SOEJIMA ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-10,12 and 14* is/are pending in the application.

4a) Of the above claim(s) *5-7 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 8/11/08, is acknowledged.

2. Claims 3, 5-10, 12 and 14 are pending.

3. Claims 5-7 and 14 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 3, 8-10 and 12 are under examination as they read on a polypeptide comprising a neutralizing epitope region in von Willebrand factor-specific cleaving protease (hereinafter, also referred to as vWFCP or ADAMTS-13), which is recognized by an antibody against the protease, or a peptide fragment derived from the polypeptide and a composition thereof.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. The specification has described several amino acid sequences that each must have a sequence identifier.

The specification discloses the following sequences RQRR and HEXXHXXGXXHD (page 2, last ¶) and RGDS on page 3 (top ¶) that fail to comply with the sequence rule. Applicant is reminded of the sequence rules which require a submission for all sequences of 10 or more nucleotides or 4 or more amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Correction is required.

5. Applicant's IDS, filed 7/10/08, is acknowledged.

6. The "an amino acid sequence" and "a polypeptide" phrases result in claims 3, 8 and 10 of very different scope, because these phrases encompasses amino acids that comprise the full-length sequence of position 449-687 of SEQ ID NO: 1 or any portion of 449-687 of SEQ ID NO: 1. This claim is anticipated by any dipeptide or larger oligopeptide. It is suggested that the claims be changed to recited "the".

7. The certified English translation of the foreign priority document JP 2003-071919 is sufficient to overcome all the rejections made under 102(a).

8. In view of the amendment filed on 7/10/08, only the following rejection is remained.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3, 8-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide of SEQ ID NO: 1, an isolated polypeptide consisting of amino acids 446-687 of SEQ ID NO: 1 and a composition thereof, does not reasonably provide enablement for a polypeptide consisting of "any" amino acid sequence from position 449-687 of SEQ ID NO: 1, a reagent fro antibody measurement comprising "any" polypeptide of claim 3 in claim 8, a "pharmaceutical composition" for "treating a patient positive for an anti-ADAMTS-13 antibody" comprising "any" polypeptide of claim 3, in claim 10, wherein the pharmaceutical composition is administered to the patient to neutralize the antibody in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action mailed 1/11/08.

Applicant's arguments, filed 7/10/08, have been fully considered, but have not been found convincing.

Applicant does not present any argument regarding the enablement rejection for the in vivo use of the claimed polypeptide. Accordingly, the rejection is maintained for reasons of record and reiterated hereby.

At issue is whether or not the claimed composition would function as pharmaceutical composition of claims 10 and 12. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition are effective for *in vivo* use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

The lack of any working examples is exacerbated because the invention is in a highly unpredictable art-treat a patient positive of anti-ADAMTS-13 antibody- and while the level of skill of in the art may be high, the state of the prior art is that it is in fact unknown and untested what are the underlying therapeutic molecule and physiologic bases of the therapeutic effects of ADAMTS-13 polypeptide in the treatment of a patient positive for an anti-ADAMTS-13 antibody. There must be a rigorous correlation of pharmacological activity between the disclosed in vitro utility and an in vivo utility to establish practical utility. "Substantiating evidence may be in the form of animal tests which constitute recognized screening procedures

with clear relevance to utility in humans. See Ex parte Krepelka, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein." Ex parte Maas, 9 USPQ2d 1746

Further, at issue the portions of the claimed polypeptide. Given, the "an amino acid sequence" and "a polypeptide" phrases result in claims 3, 8 and 10 of very different scope, because these phrases encompasses amino acids that comprise the full-length sequence of position 449-687 of SEQ ID NO: 1 or any portion of 449-687 of SEQ ID NO: 1. The specification fails to provide guidance as which portion of the amino acids 449-687 is sufficient to neutralize the anti-ADAMTS-13 autoantibodies.

11. The following rejection applies to any portion of amino acids 449-687 of SEQ ID NO:1. The "an amino acid sequence" and "a polypeptide" phrases result in claims 3, 8 and 10 of very different scope, because these phrases encompasses amino acids that comprise the full-length sequence of position 449-687 of SEQ ID NO: 1 or any portion of 449-687 of SEQ ID NO: 1. This claim is anticipated by any dipeptide or larger oligopeptide

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 3 stands rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al (J Biol Chem. 2001 Nov 2;276(44):41059-63. IDS Ref C1).

Zheng et al teach delineate the Cys-rich and the ADAMTS spacer (a specific fragment of aa449-687 of SEQ ID NO:1. Further Zheng et al teach a fragment consisting of RGDS. A fragment consisting of Cys-rich domain contains an RGDS sequence that could mediate integrin-dependent binding to platelets or other cells (see page 41062, 1st col., 1st ¶ in particular).

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 20, 2008

/Maher M. Haddad/
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